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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/03/2003

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/865,548

Applicant(s)
Barnea et al

Examiner
Michael Borin

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 28, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above, claim(s) 1-36, 40-42, 44-47, and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-39, 43, 48, and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 10/28/2002 is acknowledged. Applicant elected, without traverse, Group XIII, and peptide SEQ ID No. 13. Claims reading on the elected invention are 37-39,43,48,49¹. Claims 1-36,40-42, 44-47,50 are withdrawn from consideration as being drawn to a non-elected groups. Cancellation of claims 1-36,40-42, 44-47,50 and amendment of claims 37-39,43,48,49 to read on elected invention (peptide SEQ ID No. 13) is requested.

Title, Abstract

2. The title and abstract of the invention are not descriptive. The title and abstract do not reflect the elected invention. A new title and abstract are required which are clearly indicative of the invention to which the elected claims are directed.

Sequence Listing

3. The Sequence Listing was approved by STIC for matters of form.

¹Examiner disagrees with applicant that claims 40-42 read on the elected invention: the claims are not drawn to SEQ ID No. 13.

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Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 39,49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "in context of a ... cell" in the claims is not clear.

Claim Rejections - 35 U.S.C. § 101/ 112-1

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute

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carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

5. Claims 37-39,43,48,49 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to peptide SEQ ID No.13. Specification informs that the peptide is recovered from soluble MHC-s from HLA-A2 and is identified by computer analysis as a fragment from DNA methyl transferase (p. 65, line 20 and Table 8, p. 66). The peptide is addressed in Table 9 which demonstrate that the peptide is not

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specific to any particular cell type - it is present in all types of cells described in the Table. P. 98 mentions that parent protein, MTDM (DNA methyl transferase) is expressed in different cancer cell types; however, there is no showing that this enzyme is specific to cancer cells. Contrary, Niederreither et al teach that this enzyme is present in various tissues (see abstract). In addition, specification (p. 90, lines 43-45) teaches that only a few out of thousands of MHC-binding peptides may eventually become candidates for development of anti-cancer vaccines. No particular information about beneficial features of peptide SEQ ID No. 13 is present.

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Identifying use of the claimed polypeptide would require carrying out further research. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The potential specific utilities suggested by applicant are an invitation to do further research to search for a specific and substantial utility for each peptide modeled according to the claimed method. Further, no readily apparent well-established utility for any one peptide designed according to the method is set forth in the specification. Applicant is reminded of *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689 (1966), which stated that

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"a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

6. Claims 37-39,43,48,49 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Conclusion.

7. No claims are allowed
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 1, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

